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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/634,365 | 08/05/2003 | Clifford A. Wright | 788114-1 | 8903 |

33651 7590 04/09/2004

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EXAMINER

PATEL, MITAL B

ART UNIT PAPER NUMBER

3743

DATE MAILED: 04/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/634,365 | Applicant(s) WRIGHT, CLIFFORD A. | |
| | Examiner Mital B. Patel | Art Unit 3743 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 16-18 is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☒ Claim(s) 19 and 20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 August 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>12/22/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, a securing clip mounted to the other one of the pair of slider extension tubes must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

2. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the **range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited.** The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: There is a lack of antecedent

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basis in the specification for a securing clip mounted to the other one of said pair of slider extension tubes to help secure the other one of said pair of slider extension tubes in a fixed position relative to the user.

Claim Objections

4. Claims 2-15 are objected to because of the following informalities: Claims 2-15 set forth dependency to claim 1. Claim 1 in the preamble sets forth a cannula system. However, claims 2-15 set forth a fluid delivery system in the preamble. In order to maintain consistency throughout the claims, Applicant should clarify as to what the preamble is intended to recite, either a cannula system or a fluid delivery system and this consistency should be reflected in all of claims 1-15. Appropriate correction is required.

5. Claim 9 is objected to because of the following informalities: Claim 9 is dependent on claim 11. It is unclear to the Examiner whether Applicant intends claim 9 to be dependent off of claim 11. The dependency as set forth does not render claim 9 not examinable on the merits, however, clarification or renumbering is suggested. Appropriate correction is required.

6. Claim 19 is objected to because of the following informalities: Claim 19 sets forth a pair of extensions tubes is plugged at a distal end thereof with a stop and is adapted to be coupled at a proximate end thereof to a supply of air. However, based on the disclosure, it appears that Applicant intends to claim that one of the pair of extension tubes is plugged at its distal end whereas the other pair is adapted to be coupled to a supply of air. In considering the claims on the

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merits the Examiner has interpreted the claim to recite that the distal end of one of the pair of extension tubes is plugged with a stop while the other of the pair of extension tubes at its proximal end is adapted to be connected to a source of air. Applicant is required to make the appropriate changes to the claim language for clarification.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-11 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Bartholomew (US 5,400,776).

9. **As to claim 1**, Bartholomew teaches a cannula system (**See Fig. 2**), comprising: a nasal cannula **29** for facilitating the delivery of fluids to the lungs of a user; a pair of slider extension tubes **23** coupled to said nasal cannula; and a pair of ear pieces **11**, each ear piece having a recessed tube channel **39** (**See Fig. 4**) for receiving slidably therein an individual one of said pair of slider extension tubes to facilitate supporting from the ear piece said nasal cannula and to help facilitate adjusting the distance between the nasal cannula and individual ones of said pair of ear pieces to position said nasal cannula in proper position

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relative to the nostrils of said user for the delivery of fluids to the lungs of the user.

10. **As to claim 2**, Bartholomew teaches a system, wherein said nasal cannula includes a pair of spaced apart nasal tips **31** of sufficient length for insertion into the nostrils of the user.

11. **As to claim 3**, Bartholomew teaches a system, wherein said pair of spaced apart nasal tips have substantially smaller outer diameter than said nasal delivery tube (**See Fig. 2 which shows nasal tips 31 to be smaller in diameter than tubes 23**).

12. **As to claim 4**, Bartholomew teaches a system, wherein said pair of spaced apart nasal tips **31** are trimmable to custom fit the user (**It should be noted that although Bartholomew does not explicitly disclose nasal tips which are trimmable, the nasal tips of Bartholomew are fully capable of performing the function or are able to be trimmed because it is well known in the art that the nasal tips are made of a flexible material which material would allow for the tips to be trimmed**).

13. **As to claim 5**, Bartholomew teaches a system, wherein each individual one of said ear pieces has disposed on its proximal end a guide **43** for helping to facilitate guiding an individual one of said pair of extension tubes into a corresponding one of said recessed tube channels and to facilitate securing slidably said individual one of said pair of extension tubes to said ear piece.

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14. **As to claim 6**, Bartholomew teaches a system, wherein said nasal delivery tube includes a pair of spaced apart nasal tips **31** of sufficient length for insertion into the nostrils of a user.

15. **As to claim 7**, Bartholomew teaches a system, wherein said pair of spaced apart nasal tips have substantially smaller outer diameter than said nasal delivery tube (**See Fig. 2 which shows nasal tips 31 to be smaller in diameter than tubes 23**).

16. **As to claim 8**, Bartholomew teaches a system, wherein said pair of spaced apart nasal tips **31** are trimmable to custom fit the nostril depths of the user (**It should be noted that although Bartholomew does not explicitly disclose nasal tips which are trimmable, the nasal tips of Bartholomew are fully capable of performing the function or are able to be trimmed because it is well known in the art that the nasal tips are made of a flexible material which material would allow for the tips to be trimmed**).

17. **As to claim 9**, Bartholomew teaches a system, wherein each individual one of said ear piece recessed tube channels is sufficiently long to capture an individual one of said pair of extension tubes at two capture points **49, 51** and is sufficiently narrow at about a distal end thereof to fixedly secure (**See Col. 3, lines 18-20**) said individual one of said pair of extension tubes within said channel at one of the two capture points to help facilitate supporting said nasal cannula substantially below the nose of the user and in close proximity to the nostrils of the user.

18. **As to claim 10**, Bartholomew teaches a system, further comprising: a

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section of fluid delivery tubing **19** coupled to said at a distal end of the other one of said pair of slider extension tubes and having a fluid source connector **21** disposed at its distal end to help facilitate the delivery of fluids to the lungs of the user (**See Col. 2, lines 50-51**).

19. **As to claim 11**, Bartholomew teaches a system, further comprising: a securing clip **13** mounted to said section of fluid delivery tubing to help secure the fluid delivery tubing in a fixed position relative to the user.

20. **As to claim 14**, Bartholomew teaches a system, wherein said fluid source is a source of oxygen (**See Col. 2, lines 50-51**).

Claim Rejections - 35 USC § 103

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

22. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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23. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bartholomew (US 5,400,776).

24. **As to claim 12**, Bartholomew teaches essentially all of the limitations except for wherein the securing clip is mounted to the other one of said pair of slider extension tubes to help secure the other one of said pair of slider extension tubes in a fixed position relative to the user. It should be noted that Bartholomew does teach a securing clip **13**, however, Bartholomew does not explicitly teach the securing clip mounted to one of extension tubes **23**.

However, Bartholomew does teach that the securing clip is used to retain the cannula system to a patient's clothing to reduce patient discomfort. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide the securing clip of Bartholomew on one of the pair of extension tubes rather than on the fluid delivery tube as explicitly taught by Bartholomew so as to provide greater patient comfort, i.e., it would have been obvious to one of ordinary skill in the art to provide the securing clip anywhere on the cannula system to attach the cannula to the patient's body/clothing so as to achieve the greatest comfort.

25. Claims 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bartholomew (US 5,400,776) in view of Tiep et al (US 4,535,767).

26. **As to claim 13**, Bartholomew teaches essentially all of the limitations except for wherein said fluid source is a source of air. However, Tiep does teach a cannula system in which Tiep discloses in Col. 1, lines 9-12, that

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"Virtually everyone is aware of the fact that it is frequently necessary or advisable to deliver oxygen enriched air or other gases or gas mixtures to patients during various different types of therapy." Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a source of air as the fluid source in the system of Bartholomew as taught by Tiep depending on the type of therapy the patient is receiving.

27. **As to claim 15**, Bartholomew teaches essentially all of the limitations except for wherein said fluid source is a gas mixture source to help facilitate user breathing. However, Tiep does teach a cannula system in which Tiep discloses in Col. 1, lines 9-12, that "Virtually everyone is aware of the fact that it is frequently necessary or advisable to deliver oxygen enriched air or other gases or gas mixtures to patients during various different types of therapy." Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a gas mixture source as the fluid source in the system of Bartholomew as taught by Tiep depending on the type of therapy the patient is receiving.

Allowable Subject Matter

28. Claims 16-19 are allowed over the prior art of record.

29. Claim 20 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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30. The following is a statement of reasons for the indication of allowable subject matter: As to claims 16-18, the prior art of record does not teach nor render obvious the overall claimed combination of a method of delivery fluid to a user specifically comprising the step of placing a stop at a distal end of one of the pair of slider extension tubes and wherein the other one of the pair of slider extension tubes has a distal end adapted to be coupled to a fluid source. As to claim 19, the prior art of record does not teach nor render obvious the overall claimed combination of an oxygen delivery system having a pair of extension tubes plugged at a distal end thereof with a stop and is adapted to be coupled at a proximate end thereof to a supply of air and a pair of ear pieces with recessed channels and the pair of extension tubes cooperating with the pair of ear pieces to facilitate positioning the pair of extension tubes within the respective ones of the recessed channels to support the nasal cannula from the ears of the user with the nasal prongs inserted into the nasal cavities of the user. As to claim 20, the prior art of record does not teach nor render obvious the overall claimed combination of a cannula system wherein a stop is disposed at a distal end of one of the pair of slider extension tubes and wherein the other one of the pair of slider extension tubes has a distal end adapted to be coupled to a fluid source.

Conclusion

31. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 2003/0189492, US 2002/0112730, US 5308337, US

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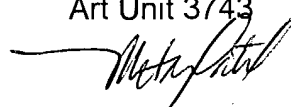
5193534, US 5105807, US 5025805, US 4559941, US 4465067, US 3682171,
and US 3209755.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 703-306-5444. The examiner can normally be reached on Monday-Friday (8:00 - 4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mital B. Patel
Examiner
Art Unit 3743



4/4/04